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Display Date	8-12-99
Publication Date	8-13-99
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 96F-0415]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;
Petroleum Wax**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of poly(alkylmethacrylate) as a processing aid in the manufacture of petroleum wax. This action is in response to a petition filed by Nalco/Exxon Energy Chemicals.

DATES: This regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*). The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 172.886(c)(2) (21 CFR 172.886(c)(2)), effective (*insert date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3076.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 14, 1996 (61 FR 58417), FDA announced that a food additive petition (FAP 7A4524) had been filed by Nalco/Exxon Energy Chemicals, L. P., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 172.886 *Petroleum wax* to provide for the safe use of poly(alkylmethacrylate) as a processing aid in the manufacture of petroleum wax.

Based on the data in the petition and other relevant material, the agency has determined that: (1) Poly(alkylmethacrylate) closely resembles and functions as poly(alkylacrylate), which is currently listed in § 172.886(c)(2) for use as a processing aid in the manufacture of petroleum wax; (2) poly(alkylmethacrylate) is a high molecular weight polymer whose absorption across the gastrointestinal membrane would be minimal; and (3) the estimated daily intake of the monomeric impurity alkylmethacrylates from the proposed use, 0.1 milligram (mg)/person/day (d), is well below the acceptable daily intake of 30 mg/person/d established for alkylmethacrylates by the agency. Furthermore, the agency has determined that two methods incorporated by reference in § 172.886(c)(2) for the analysis of poly(alkylacrylate) entitled “Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax” and “Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax,” are applicable to the analysis of poly(alkylmethacrylate). Based on this information, FDA concludes that the proposed food use of poly(alkylmethacrylate) as a processing aid in the manufacture of petroleum wax is safe, the additive will achieve its intended technical effect, and therefore, 21 CFR part 172 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents

any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.886 is amended by revising paragraph (c)(2) to read as follows:

§ 172.886 Petroleum wax.

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(c) * * *

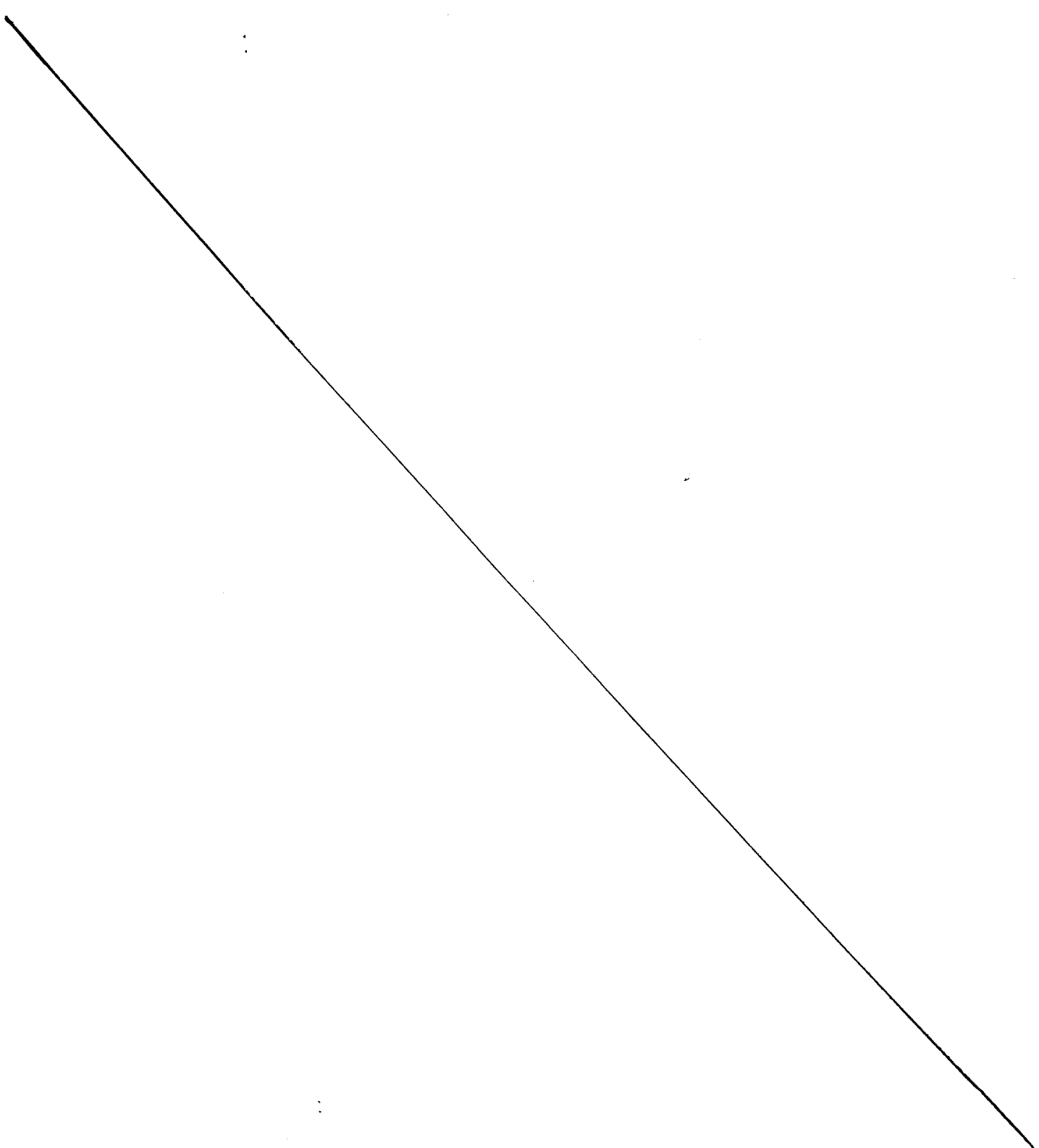
(2) Poly(alkylacrylate) (CAS Reg. No. 27029–57–8), made from long chain (C_{16} – C_{22}) alcohols and acrylic acid, or poly(alkylmethacrylate) (CAS Reg. No. 179529–36–3), made from long chain (C_{18} – C_{22}) methacrylate esters, having:

(i) A number average molecular weight between 40,000 and 100,000;

(ii) a weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and

(iii) unreacted alkylacrylate or alkylmethacrylate monomer content not in excess of 14 percent, as determined by a method entitled “Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug

Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) or poly(alkylmethacrylate) residues as determined by a method entitled "Method for Determining Residual Level of Poly(alkylacrylate)



in Petroleum Wax," which is incorporated by reference. Copies are available from the addresses
→ cited in this paragraph. * * * * *

Dated: 8/5/99
August 5, 1999

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Janice F. Oliver

Janice F. Oliver
Deputy Director
Center for Food Safety and Applied Nutrition

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

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Michael W. Bell